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10/681,750	10/07/2003	Philipp Lang	2960/113	8141

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EXAMINER	
MONTANO, MELISSA ANN	

ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## *Office Action Summary*	**Application No.** 10/681,750	**Applicant(s)** LANG ET AL.	
	Examiner MELISSA MONTANO	**Art Unit** 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,8,9,11-17,20,42,51 and 96-137* is/are pending in the application.

4a) Of the above claim(s) *114-136* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,8,9,11-17,20,42,51,96-113 and 137* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/5/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed 5/26/2009 has been entered. The previous rejections under 35 USC 112 2nd paragraph are withdrawn in view of applicant's amendments to the claims. Claims 1, 3, 8, 9, 11-17, 20, 42, 51 and 96-137 are pending in this application.

2. Newly submitted claims 114-136 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 114-136 are directed to the non-elected species of a tibial implant.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 114-136 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Objections

3. Claim 13 is objected to because of the following informalities: Claim 13 recites "the relative orientation", which appears to be lacking antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 109 and 110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 109 and 110 recite the limitations "at least one component" and "two or more components", respectively. The examiner is unsure whether applicant is referring to the femoral and tibial components recited in claim 1 or different, completely separate components. Clarification of these limitations is requested.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 20, 42, 51, 96-99, 104, 109, 110, 112, 113, and 137 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,423,828 to Benson (Benson).

Regarding at least claims 1, 99, 104, and 137

Benson teaches a method and apparatus for use in bone joint replacement surgery for insuring that the replacement prosthesis is properly sized so that the resulting joint movement between fully extended and flexed positions mimics the original range of movement enjoyed by the patient prior to degeneration of the joint (col. 3, lines 42-48). Benson also teaches that it is possible to customize the components of the prosthesis as necessary in order to replicate the proper knee dimensions for the individual patient (col. 6, lines 1-3). In order to do this, a flexible measure cable is extended across the joint to be replaced and two measurements (patient specific measurements) are made (col. 3, lines 49-51), one while the bones are in the extended position and the other while the bones are in the flexed position (col. 4, lines 55-68 and col. 5, lines 1-4). The measured distances are used to select and fit joint replacement prosthetic components (col. 5, lines 19-21).

The prosthesis taught by Benson includes a femoral component, which inherently includes a superior surface (bone-abutting surface) configured to oppose and be fixed to at least a portion of a femur and an inferior surface (articular surface) configured to oppose and articulate with at least a portion of a tibial implant surface, as claimed by applicant (see fig. 2 and 5A-5B).

The examiner asserts that the measurements used to select and fit joint replacement prosthetic components, as taught by Benson, inherently imply that the inferior surface/articular surface of the implant is configured based in part on pre-existing parameters and in part on or more patient specific measurements of the joint, as claimed by applicant.

Regarding at least claims 3 and 113

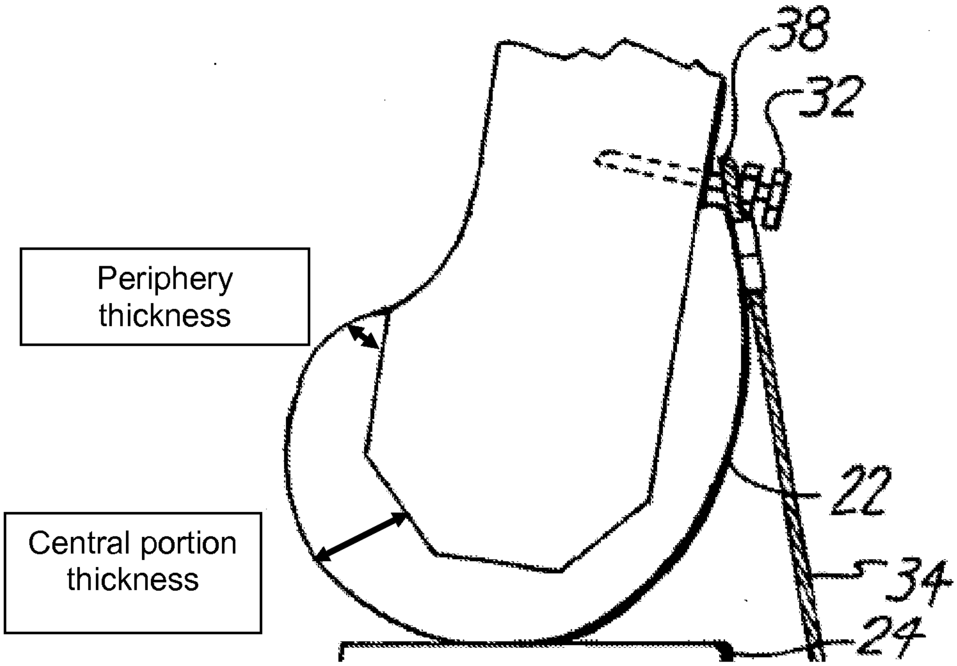
According to Benson, inaccurate sizing of the joint prosthesis can be avoided by providing a plurality of measurements between respective fixed points of the bone making up the joint in both the extended and flexed positions prior to resection of the bones themselves (col. 6, lines 4-12). In this fashion, joint components of suitable dimensions, including thickness, may be selected to reproduce the patient's original joint dimensions or to correct the joint dimensions to overcome degeneration of the patient’s joint (col. 4, lines 8-12). The examiner asserts that Benson’s contemplation of using the prosthesis for correcting the joint dimensions, including thickness, to overcome degeneration of the joint would inherently imply that the implant has a thickness of a cartilage defect in a patient, as claimed by applicant. The prosthesis taught by Benson would also inherently alter the load bearing ability relative to the joint, as claimed by applicant.

Regarding at least claims 20, 96, and 97

Benson also teaches that in practice, manufacturers of knee prostheses provide a selection of different sizes and shapes of femoral implants (22) and tibial implants (24); thereby allowing the surgeon to choose the size best suited to the patient’s needs (col. 5, lines 57-59 and 67-68). The examiner asserts that this would necessarily constitute an implant that is configured based on a pre-existing library of implants and/or a library of pre-existing shapes, as claimed by applicant. Benson further teaches the use of trial implants which are placed on the resected bones prior to selecting a prosthetic component of the desired fit and leg length (col. 7, lines 16-20). Because the prosthetic components taught by Benson are configured based on the dimensions of the trial implants, the examiner considers the trial implants to be the same as the mold claimed by applicant.

Regarding at least claims 42, 51, 98, and 112

Figures 5A and 5B of Benson clearly show that the femoral implant (22) has a profile that approximates the contour of the subchondral bone and that the superior surface is configured to be placed against a bone cut for use in a multi-compartmental knee replacement, as claimed by applicant. Also seen from figures 5A and 5B of Benson, is that a central portion of the implant is of greater thickness than at least a portion of a periphery. See drawing below.



Regarding at least claims 109 and 110

The prosthesis taught by Benson includes a femoral component (22) and a tibial implant (24) typically used with a tibial tray (25) that will contact the femoral component

(22) (col. 5, lines 48-51 and 59-64). The examiner asserts that the tibial tray (25) would necessarily constitute at least one component that engages the joint in a slideable or rotatable fashion. Further, the examiner asserts that the femoral component, tibial implant, and tibial tray taught by Benson would necessarily constitute two or more components that are slideably engaged, as claimed by applicant.

Regarding at least claims 1, 3, 20, 42, 51, 96-99, 104, 109, 110, 112, 113, and 137

The examiner notes the use of functional language throughout the claims, such as the "configured to" and "wherein" clauses. Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure. See MPEP 2111.04. Further, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 100-103 and 105-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benson.

Benson teaches the invention substantially as claimed according to claims 99 and 104 (see rejection of claims 99 and 104 above). However, Benson does not explicitly teach that the patient specific measurement is a width in the mediolateral direction, a length in the anteroposterior direction, a curvature in the coronal or sagittal plane, or any combination of those.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Benson to include that the patient specific measurement is a width in the mediolateral direction, a length in the anteroposterior direction, a curvature in the coronal or sagittal plane, or any combination of those, since the purpose of the invention is to provide an implant that is properly sized so that the resulting joint movement mimics the original range of movement enjoyed by the patient prior to degeneration of the joint (col. 3, lines 42-49). It would have been obvious to one having ordinary skill in the art to try making and using each of the measurements claimed in order to replicate the proper knee dimensions for the individual patient (col. 6, lines 1-3), as taught by Benson.

10. Claims 8, 9, 11-14, and 111 rejected under 35 U.S.C. 103(a) as being unpatentable over Benson in view of US Patent No. 5,690,635 to Matsen, III et al. (Matsen).

Benson teaches the invention substantially as claimed according to claim 1. However, Benson does not explicitly teach specific materials used for the construction or composition of the femoral implant, structures for attachment, or a uses as a uni-compartmental knee replacement.

Matsen teaches an apparatus and methods applicable in surgical situations in which the precise positioning of a tool in relation to a patient is an integral part of the surgery (col. 1, lines 16-19). An example of a surgical procedure that requires accurate geometric solutions, as well as the evaluation of specific patient physiological characteristics, is total knee arthoplasty (TKA), where the distal femur and the proximal tibia are resected and replaced by prosthetic components made of metal and plastic, for the purpose of closely mimicking the natural anatomy of the knee (col. 1, lines 56-67 and col. 2, lines 1-5).

Matsen also teaches a femoral prosthesis (10) used to replace the end of a femur bone (12) when the bone is damaged or diseased. The exterior surface (26) of the prosthesis simulates the distal end of a normal femur, including the condyles and notch margin (col. 9, lines 16-25). The geometric relationships that make up the inferior surface (28) of the prosthesis are the same as those that define the bone preparation tasks. Additionally, two anchoring studs (plurality of structures for attachment; 38 and 39) extend normally from the inferior surface (28) in what is shown as a symmetrical orientation (fig. 1) and correspond with stud holes that are drilled in the (col. 9, lines 46-63).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Benson to include specific materials used for the construction or composition of the femoral implant, particularly in view of the lack of any disclosed criticality for the claimed limitations, and also in order to closely mimic the natural anatomy of the knee, as taught by Benson. Further, it would have been obvious to use the claimed materials for the construction and/or composition of the implant since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Though Matsen does not explicitly teach the use of one or more biologically active materials, the examiner asserts that it is well known in the art that biologically active materials are advantageous when applied to prosthetic implants such as those taught by Matsen (see for example US Patent Application Publication No. 2002/0111694 A1 to Ellingsen et al.).

It also would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Benson to include structures for attachment, as well as use in a uni-compartmental knee replacement, in order to properly fix the prosthesis to the resected bone surface so that the diseased or damaged portion of the joint can be replaced, as taught by Matsen. Though Matsen does not explicitly teach a use of the disclosed prosthesis in a uni-compartmental knee replacement, the examiner asserts that it would have been obvious to apply the apparatus and method of Matsen to any type of knee replacement surgery since the final outcome of replacing any damaged or diseased bone is the same.

11. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benson in view of US Patent No. 3,852,830 to Marmor (Marmor).

Benson teaches the invention substantially as claimed according to claim 1 (see rejection of claim 1 above). However, Benson does not explicitly teach a peripheral structure.

Marmor teaches a knee prosthesis for total or partial replacement of the articulating portions of the knee, including a femoral component (11) body (13) having side edges (peripheral structure; 13', 13", 15', and 15") that are curved or turned upwardly, for the purpose of trapping cement to prevent it from leaking out as much as possible and to obtain better fixation (col. 3, lines 1-3). The examiner asserts that the side edges of Marmor are shown to extend along an entire periphery of the implant (fig. 3 and 4).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Benson to include upwardly curved side edges along the periphery of the femoral component in order to trap cement to prevent it from leaking out and to obtain better fixation, as taught by Marmor. It would also have been obvious to extend this peripheral structure along an entire perimeter or only a portion of a perimeter of the implant, particularly in view of the lack of any disclosed criticality of the claimed limitations.

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA MONTANO whose telephone number is (571)270-5785. The examiner can normally be reached on Monday-Friday 8:00AM-5:00PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM

/Bruce E Snow/
Primary Examiner, Art Unit 3738